

Hughes 3D Printed HEPA Filter Mask

Care instructions V6.5 - 9

Appropriate Use Criteria

This is a supplementary face mask and its intent is to be used as emergency backfill in the event of Personal Protective Equipment (PPE) shortages if/when the option of traditional PPE devices have become unavailable. Its original intent is to be used as a community mask, to be used by the general public to slow the spread of COVID19. This device has not gone through the same regulatory approval process as traditional PPE and should be regarded as emergency or supplemental use only.

This device is **not** suitable protection against airborne exposures and should **not** be used as a replacement for a N95 mask, PAPR device, or any other respirator device. Per CDC Guidelines (42 CFR Part 84) N95 masks must meet test standards of filtering airborne aerosol with a mass median aerodynamic diameter particle of about 0.3 μm . This supplementary face mask **DOES NOT MEET REQUIREMENTS FOR AIRBORNE PRECAUTIONS** and **SHOULD NOT BE USED DURING AEROSOL GENERATING PROCEDURES**. This supplementary mask **should not be used in a clinical setting** where the infection risk level through inhalation exposure is high. This version of the mask as of the printing of this document has yet to be approved by the NIH, but is queued for review. Use of this mask is at the discretion of user and should only be used when all other PPE is unavailable.

This mask can however be used in situations where the risk of community spread is high, as a suitable alternative to a cloth mask or other types of face coverings which do not filter to the same requirements of an N95. Examples of community uses of this mask are but not limited to those in the mental health field, shop keepers, postal service workers, etc.

The information included in this document provides device description and feature overview, recommended assembly steps, and cleaning instructions for reuse.

Attention:

Inspect your mask for foreign objects before donning everytime. This will ensure you do not breathe in a random piece of lint or random object which has somehow made it into your mask.

Device Overview

The Quick Print V6.5 HEPA Filter Mask consists of three main components (the TPU mask flexible body, PLA/PETG hard shell and the HEPA filter w/ filter housing) and six supplementary components (the PLA/PETG strap clips and the two elastic straps, two pieces of ribbon, or two cords of 1.75mm TPU). A diagram of the components is shown below in Fig. 1.

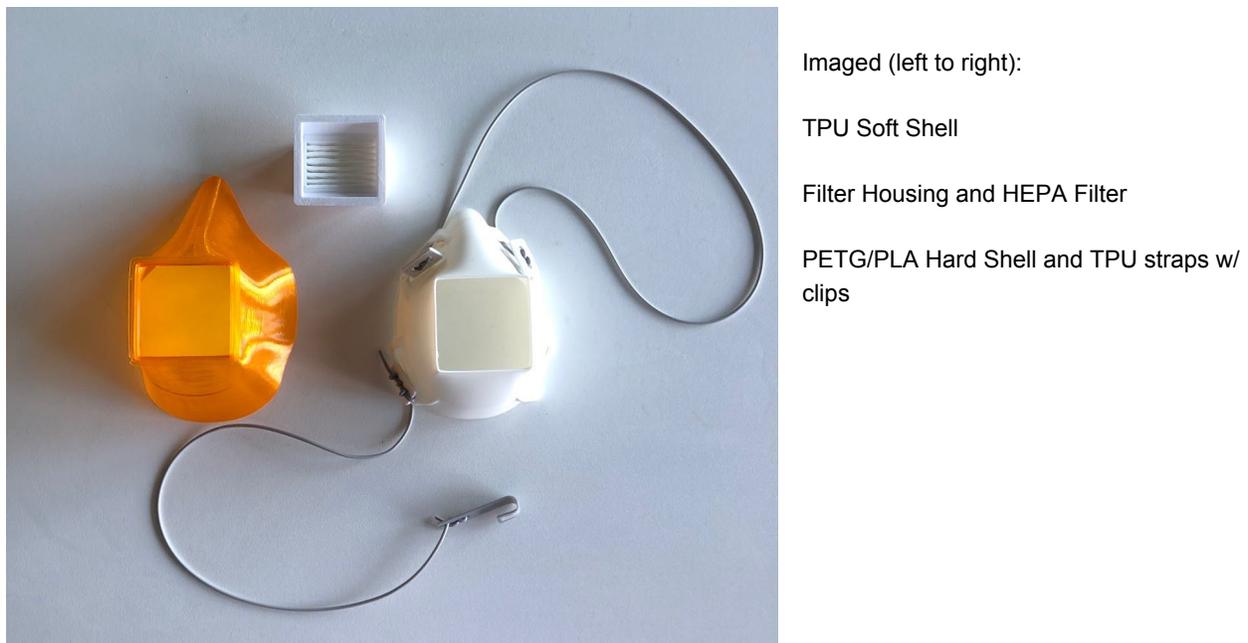


Fig 1. Diagram of the QuickPrint V7 HEPA Filter Mask components

Versions 6.5-8 are designed to receive a 700 series iRobot Roomba vacuum HEPA Filter that can be inserted into the filter housing once removed from the originally manufactured housing.

In Versions 9 and later a CPAP ultra fine PC filter is used and cut to size.

At this time it is recommended that the entire mask is decontaminated after use period (with the decontamination instructions provided in Appendix A). If alternate filter material is used with this supplemental mask please refer to CDC guidelines and other appropriate materials as these are updated almost daily at the time of writing this document. See Appendix B for known guidelines on filter material selection.

Assembly of Straps: Everyone has different head shapes and sizes, thus this mask has been designed to accommodate different orientations of wear. In this package you have received 4 strap clips and a length or lengths of strap material (Extruded TPU, Elastic, or Ribbon).

The two main ways of assembling the straps are as follows.

Over the ears:

- Anchor your first strap in the method provided in the video link via the QR code below.
- Take the first strap and run it from the top anchor point to the bottom anchor point.
- Adjust the strap to hold the mask to your face loosely whereas the strap goes over and around your ear.
- Repeat this for the left/right side.
- The mask should not fit so snugly that it creates a ring on your face but rather sits on your face comfortably.
- Continue to adjust the straps until you can loosely place a palm over the air intake of the mask and breathe in. The mask should pull tight to your face.

Over the head:

- Anchor your first strap in the method provided in the video link via the QR code below.
- Take the first strap and run it from the top anchor point to the opposite top anchor point. Anchor both ends with the clips on the outside of the hard shell.
- Adjust the strap to hold the mask to your face loosely whereas the strap goes over and around the top of your head and above your ear.
- Repeat this for the two bottom anchor points.
- The mask should not fit so snugly that it creates a ring on your face but rather sits on your face comfortably.
- Continue to adjust the straps until you can loosely place a palm over the air intake of the mask and breathe in. The mask should pull tight to your face.

Link to strap anchor instructional video: on my instagram



Fitting the HEPA Mask

The mask itself is printed in two types of thermoplastic (TPU and PLA/PETG). In order to have the best fit to one's face I recommend heat forming the TPU portion to the user's face but **THIS REQUIRES HEAT AND A USER MUST BE ABSOLUTELY SURE THE MASK IS NOT GOING TO BURN THEIR FACE WHEN ATTEMPTING THIS!**

- 1.) Prepare a pot of boiling water and set the mask away from the heat source.
- 2.) **Dip the face side of the mask into the water for approximately 5 seconds. Do not allow the hard shell to touch the water as you want that part to stay rigid and in its original form. DO NOT expose the mask for longer than 5 seconds as it will become too hot and you risk burn yourself when fitting.**
- 3.) Touch the warm portions of the mask to your wrist ensuring it is warm to the touch but not too hot (like a baby bottle). You want the mask to be about as hot as a hot cloth or hot bath.
- 4.) Press the warm mask to your face and wiggle it around.
- 5.) Repeat the above steps until you have a fitted mask.

Recommended Cleaning

The recommended materials selected for making the reusable components of this supplemental face mask have a proven track record for remaining stable during and after the use of the list of disinfectants and sterilization process outlined in Appendix A. However, there has been no formal testing completed yet to support the claim that the use of disinfectants alone is a sufficient cleaning approach against the COVID19 virus specifically on the surface of this material.

Because of this, we recommend that the following disinfection and sterilization steps are performed after each user is finished using the supplemental mask and the user has followed the proper procedures for doffing the device.

1. Perform hand hygiene procedures and remove mask.
2. Submerge mask in a solution of **COLD WATER** combined with **hydroperoxide (five caps of hydroperoxide for every half gallon of water)**, for a duration of 4 minutes (Ensure the mask is submerged for a duration of no less than 4 minutes as defined by the EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2).
3. Remove mask from cleaning solution and rinse with cold water.
4. Perform hand hygiene procedures again.
5. Wipe down the entire mask with sterile cotton cloth to dry.
6. Set the mask aside in a clean environment to dry completely

7. Once dry place the mask in a bag for storage for next use.

(Tip: If you are cleaning your own mask you can don the mask, and blow out the filter to release the remaining water. This allows the mask to dry faster).

Optional Face Shield Attachment

If attaching the optional face shield, fully assemble the face mask then slide the straps and TPU soft shell through the hole in the center of the shield. Make sure to line up the nose ;)

Appendix A: Recommended Disinfectants and Sterilization Methods

Recommended Disinfecting Agents:

From the [EPA guidelines in List N: Disinfectants for Use Against SARS-CoV-2](#), it is recommended to use the following solutions for the disinfecting procedures of this device.

1. 10% Hydrogen peroxide solution
2. Super Sani-Cloth
3. CaviWipes
4. Hydrogen peroxide
5. Soap and water

Appendix B: Recommended Filter Materials

The level of protection provided by the supplementary mask will be determined in part by the filter material used. It is recommended that the user only use 700 series iRobot Roomba HEPA filters, as that the mask was only designed to nest with those parts.

Cut to size CPAP ULTRA FINE Filter.

